UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,598	01/18/2005	Stefano De Luigi Brushci	451225-new	2778
Mark P Levy	7590 06/06/200	8	EXAM	IINER
Thomson Hine 2000 Courthouse Plaza NE 10 West Second Street Dayton, OH 45402-1758			CESIN, ANDREI	
			ART UNIT	PAPER NUMBER
			4172	
			MAIL DATE	DELIVERY MODE
			06/06/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
Office Action Commons	10/521,598	DE LUIGI BRUSHCI ET AL.				
Office Action Summary	Examiner	Art Unit				
	ANDREI CESIN	4172				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be tim ill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONEI	Lely filed the mailing date of this communication. (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on						
	- action is non-final.					
3) Since this application is in condition for allowan	<del></del>					
closed in accordance with the practice under E	x <i>parte Quayle</i> , 1935 C.D. 11, 45	3 O.G. 213.				
Disposition of Claims						
4)⊠ Claim(s) <u>1-13</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdraw	vn from consideration					
5) Claim(s) is/are allowed.						
6) Claim(s) is/are rejected.	·					
7) Claim(s) is/are objected to.						
8) Claim(s) <u>1-13</u> are subject to restriction and/or e	election requirement					
	nootion roquironnone.					
Application Papers						
9)☐ The specification is objected to by the Examiner	r.					
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the o	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correcti	on is required if the drawing(s) is obj	ected to. See 37 CFR 1.121(d).				
11)☐ The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.				
Priority under 35 U.S.C. § 119						
<ul> <li>12) Acknowledgment is made of a claim for foreign</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents</li> <li>2. Certified copies of the priority documents</li> <li>3. Copies of the certified copies of the priority</li> <li>application from the International Bureau</li> </ul>	s have been received. s have been received in Application ity documents have been receive	on No				
* See the attached detailed Office action for a list of		d.				
Attachment(s)						
1) Notice of References Cited (PTO-892)	4) Interview Summary					
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08)	Paper No(s)/Mail Da 5) Notice of Informal Pa					
Paper No(s)/Mail Date	6) Other:	•				

## **DETAILED ACTION**

#### Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121: Claims 1-9, drawn to a process comprising a coating method for microcapsules involving a primary coating method of phase separation microencapsulation or fluidized bed coating, and a secondary coating process which is applied by spray of solution or suspension of acrylic polymer onto the particles, suspended in a fluidized bed., classified in class 427, subclass 2.100.

Claim 10-13, drawn to a product of a microcapsule containing drug primarily coated with ethylcelulose and secondarily coated with acrylic polymer, classified in class 424, subclass 474.

A telephone call was made to Mark Levy on 06/05/08 to request an oral election to the above restriction requirement, but did not result in an election being made.

# Patentably distinct Inventions

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case US,6238,703 teaches the coating of ethycellulose as being done by the alternate layering technique of either rotor granulation or pan coating [column 3, line 30]. Therefore, this reference teaches an alternate method of forming a coating method in order to apply the ethycellulose. And this alternate coating technique can be used to apply the same material to thus produce a same or similar microcapsule. Thus, as evidenced by the prior art of the record, the claimed invention of group II can be done by a materially different process.

### Search Burden

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

the inventions have acquired a separate status in the art in view of their different classification;

Art Unit: 1792

the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

the prior art applicable to one invention would not likely be applicable to another invention;

the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete <u>must</u> include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

It is noted that US 6238703 teaches the alternate technique of forming a ethycellulose coating. Thus, as evidenced by prior art of the record, the claimed invention of group II class 424, subclass 474 can be practiced by materially different process. Furthermore, it is clear that the teaching of said reference is not applicable to any other invention(s) claimed. Thus, each

invention is considered to be patentably distinct to each other, and the search required for entire inventions are burdensome.

### Conclusion

No claim is allowed.

All pending claims are subject to restriction/election requirement.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner's name whose telephone number 571-270-5349. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim be reached on 571-272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0138.

Application/Control Number: 10/521,598 Page 6

Art Unit: 1792

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/AC/ June 6, 2008 Art unit 4172

/Alain L. Bashore/ Primary Examiner, Art Unit 1792